Wilusz, Catherine

From: Burk, Suzann
Sent: Wednesday, June 5, 2019 11:54 AM
To: (b) (4)
Subject: FDA Request Permission to Disclose Information

Dear (b) (4)

My name is Suzann Burk. I am the director of the Division of Disclosure and Oversight Management at CBER/FDA.

The FDA has prepared an FMT Safety Communication which contains information that may be proprietary to (b) (4) (b) (4) CBER FDA would like to post the FMT Safety Communication to its website and as such, seeks your permission to release the information in the FMT Safety Communication that may be proprietary to (b) (4) (b) (4)

The statements that we seek permission to disclose are below in bold:

The agency is now aware of infections caused by multi-drug resistant organisms (MDRO) that have occurred following investigational use of FMT due to transmission of a MDRO from an FMT product.

Summary of the Issue

- **Two immunocompromised adults who received FMT products (b) (4) (b) (4) developed invasive infections caused by extended-spectrum beta-lactamase (ESBL)-producing *Escherichia coli* (*E.coli*). One of the individuals died.**
- **The FMT products used in these two individuals were prepared from stool obtained from the same donor.**
- **The donor stool and resulting FMT products used in these two individuals were not tested for ESBL-producing gram-negative organisms prior to use. After these adverse events occurred, stored preparations of FMT product from this stool donor were tested and found to be positive for ESBL-producing *E. coli* identical to the organisms isolated from the two patients.**

If you agree, please provide permission to disclose the information in bold above by copying the recommended release statements below on company letterhead, signing and returning it to me as a pdf file. We recommend that the release contain the following elements:

I confirm that I am authorized to speak on behalf of _____on this matter.
I confirm that ____ is the sole owner of this information.
I understand that FDA intends to disclose this information publicly, and I consent to such disclosure.
I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331(j), and 5 U.S.C. § 552(b)(4) and that is exempt from public disclosure.
I understand that after disclosure, this information will no longer be considered confidential commercial information or a trade secret under 5 U.S.C. 552(b)(4) or FDA's regulations.
I understand that, after disclosure, information in documents containing such information could not be withheld under 5 U.S.C. 552(b)(4) or FDA's regulations and I agree to hold FDA harmless for any injury caused by FDA's sharing information pursuant to this letter.
I give FDA permission to disclose the following concerning our product: _____

Signed_____
Date_____
Contact information_____

Thank you,
Suzy

Suzann Burk
Director, Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
CBER/FDA
10903 New Hampshire Ave, WO71-1007
Silver Spring MD 20993

suzann.burk@fda.hhs.gov
240-402-8028

Wilusz, Catherine

From: (b) (4)
Sent: Friday, June 7, 2019 11:44 AM
To: Burk, Suzann
Cc: (b) (4) (b) (4)

Subject: FDA Report 6.7.2019
Attachments: FDA Report 6.7.2019.pdf

Dear Ms. Burk,

Please find attached the requested statement. Note that I revised the statements minimally to be most factually accurate.
I'm copying (b) (4)
Will this only be posted, or will it also be emailed or in any other way distributed, i.e. via the "What's New at CBER?" mailing (b) (4)

Thank you.

(b) (4)

(b) (4)

June 7, 2019

To: Suzann Burk
Director, Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
CBER/FDA
10903 New Hampshire Ave, WO71-1007
Silver Spring MD 20993
suzann.burk@fda.hhs.gov
240-402-8028

From: (b) (4)

I confirm that I am authorized to speak on (b) (4) matter described below.
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I give FDA permission to disclose the following concerning our product:

(b) (4)

The agency is now aware of infections caused by multi-drug resistant organisms (MDRO) that have occurred following investigational use of FMT due to transmission of a MDRO from an FMT product.

Summary of the Issue

Two immunocompromised adults who received FMT products (b) (4) (b) (4) developed bloodstream infection caused by extended-

(b) (4)

spectrum beta-lactamase (ESBL)-producing *Escherichia coli* (*E.coli*). One of the individuals subsequently died.

The FMT products used in these two individuals were prepared from stool obtained from the same donor.

The donor stool and resulting FMT products used in these two individuals were not tested for ESBL-producing gram-negative organisms prior to use. After these adverse events occurred, stored preparations of FMT product from this stool donor were tested and found to be positive for ESBL-producing *E. coli* identical to the organisms isolated from the two patients.

Wilusz, Catherine

From: Burk, Suzann
Sent: Monday, June 10, 2019 11:14 AM
To: (b) (4)
Cc: (b) (4) (b) (4)
Subject: RE: FDA Report 6.7.2019

Hello (b) (4)

I write to follow-up regarding your question below. The "What's New at CBER" email goes out at the end of each day with a listing of everything that was posted that day. A reference to the Safety Communication likely will be included in the "What's New at CBER" email on the day that it is posted.

Thank you,
Suzy

From: Burk, Suzann
Sent: Friday, June 07, 2019 11:53 AM
To:
Cc: (b) (4) (b) (4)
Subject: RE: FDA Report 6.7.2019

Thank you (b) (4) I will inquire about the distribution and get back to you soonest.

Suzy

From: (b) (4)
Sent: Friday, June 07, 2019 11:44 AM
To: Burk, Suzann <Suzann.Burk@fda.hhs.gov>
(b) (4)
Subject: FDA Report 6.7.2019

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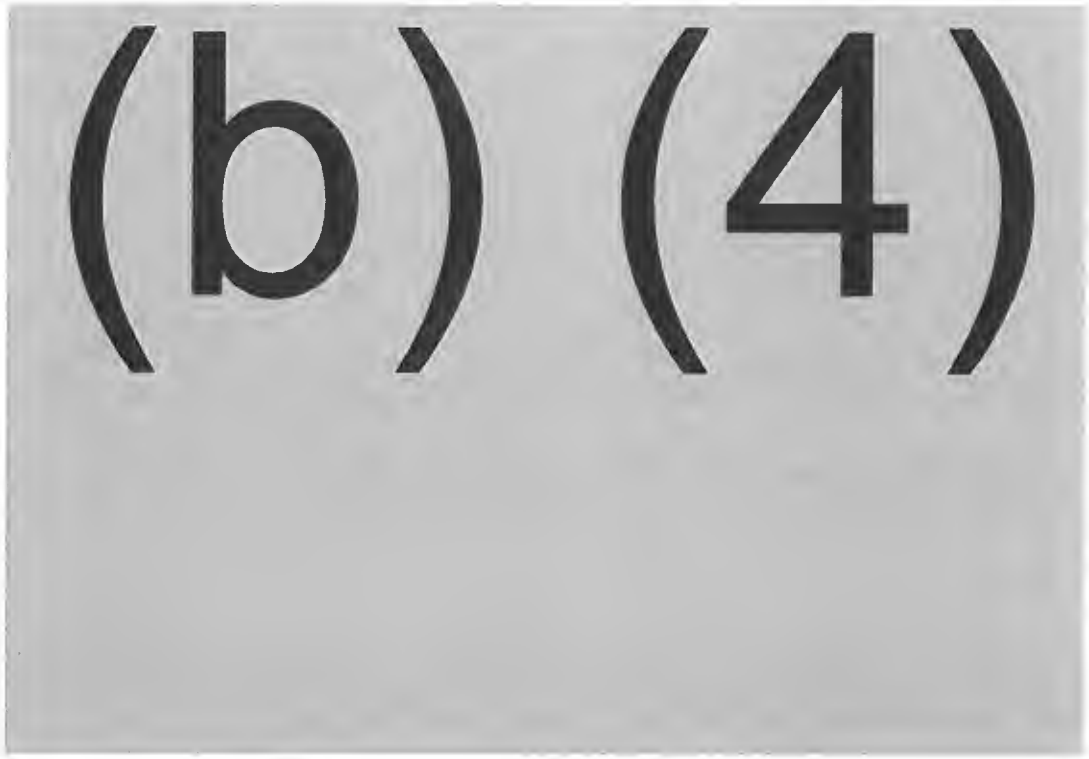
(b) (4)


(b) (4)

Wilusz, Catherine

From: (b) (4)
Sent: Monday, June 10, 2019 11:19 AM
To: Burk, Suzann
Cc: (b) (4)
Subject: RE: FDA Report 6.7.2019

Thank you. That's what I expected.

(b) (4)

From: Burk, Suzann <Suzann.Burk@fda.hhs.gov>
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To: (b) (4)
Cc: (b) (4)
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External Email - Use Caution

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